Jason M. Kerr (8222)
Ronald F. Price (5535)
John P. Snow (10735)
Steven W. Garff (13707)
Alan Dunaway (13514)
PRICE PARKINSON & KERR, PLLC
5742 West Harold Gatty Drive
Salt Lake City, Utah 84116
Telephone: (801) 530-2900
jasonkerr@ppktrial.com
ronprice@ppktrial.com
johnsnow@ppktrial.com
steven.garff@ppktrial.com
alandunaway@ppktrial.com

Evan S. Strassberg (8279)
MICHAEL BEST & FRIEDRICH, LLP
2750 East Cottonwood Pkwy, Suite 560
Cottonwood Heights, Utah 84121
Telephone: (801) 833-0500
Facsimile: (801) 931-2500
E-mail: esstrassberg@michaelbest.com

Robert Housman (D.C. Bar No. #471099)
(admitted pro hac vice)
BOOK HILL PARTNERS LLC
9001 Clifford Ave
Chevy Chase, MD 20815
Telephone: (202) 486-5874
rhousman@bookhillpartners.com

Attorneys for Defendants XLEAR, Inc. and Nathan Jones

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF UTAH, CENTRAL DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. XLEAR, INC., a corporation, and NATHAN JONES, individually and as an Officer of XLEAR, INC. Defendants.	**DEFENDANTS' MOTION FOR JUDGMENT ON THE PLEADINGS (FED. R. CIV. P. 12(C))** Case No. 2:21-cv-00640-RJS-DBP Judge Robert J. Shelby Magistrate Judge Dustin B. Pead

Pursuant to Fed. R. Civ. P. 12(c), Defendants respectfully move this Court to enter judgment on the pleadings and dismiss with prejudice the two claims the United States of America, acting on behalf of the Federal Trade Commission (the "Commission"), has asserted against Defendants in the Complaint [ECF No. 2].

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INTRODUCTION AND SUMMARY OF RELIEF SOUGHT

The Commission's claims should be dismissed because they seek relief that is not available or supported by the plain language of the FTC Act. The Complaint asserts two causes of action, both of which hinge on whether Defendants engaged in "deceptive acts or practices" under sections 5(a) and 12 of the FTC Act. But fatally, the Complaint fails to allege any facts that constitute "deceptive acts or practices" within the plain meaning of the statute. Instead, the Complaint alleges that Defendants violated the statute by making advertising claims that were not substantiated by randomized clinical trials. But the language of the statute nowhere requires substantiation, let alone substantiation through clinical trials. The substantiation standard the FTC seeks to impose on Defendants is merely a self-created standard the Commission attempts to employ by agency fiat. Because the Complaint fails to allege facts demonstrating that Defendants engaged in any "deceptive acts or practices," it should be dismissed with prejudice.

The same result ensues even if the FTC Act's "deceptive acts or practices" language were deemed ambiguous enough to entertain and evaluate the Commission's position. Neither the word "substantiation" nor any derivatives thereof appear in the relevant provisions of the FTC Act. Congress could have, but has not, included such language in the statute had it so desired. Indeed, Congress has done so for a small subsection of marketers to which the FTC Act applies. Had Congress wanted a substantiation requirement to apply to *all* advertisers, it would have so mandated. Moreover, application of the Commission's position leads to unfavored Constitutional restrictions on mixed speech and improperly shifts the burden of proof from the government to Defendants.

The history of interpretation and enforcement of the FTC Act likewise weighs against the Commission's claims. The concept of "substantiation" did not appear anywhere in FTC

enforcement actions during the first 60 years following enactment of the FTC Act. And even when it did finally appear, it was only invoked as a means to "fence in" parties that had *already been found* to violate the plain language of the FTC Act. The Commission's attempt to invoke this fencing-in standard against Defendants who have not been found guilty of any wrongdoing has no foundation. Indeed, the Commission's current position contradicts years of its own policies and precedents. Additionally, to the extent the Commission heretofore would have relied on *Chevron* deference for help here,[1] under *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024), that avenue is blocked.

Lastly, even assuming *arguendo* that the FTC Act indeed requires some form of substantiation, the Complaint's claims rest on a non-existent requirement that such substantiation must take the specific form of randomized, clinical trials. No language in the statute or history of enforcement or interpretation supports this position. Yet the Commission's claims hinge on it. For these and other reasons, as shown below, the Motion should be granted and judgment on the pleadings entered for Defendants.

LEGAL STANDARD

> Once "the pleadings are closed," Rule 12(c) permits a party to "move for judgment on the pleadings." A Rule 12(c) motion is subject to the same standards as a Rule 12(b)(6) motion. Thus, "to survive judgment on the pleadings, [a plaintiff] must allege a claim to relief that is plausible on its face." To determine plausibility, the court "examine[s] the elements of the particular claim and review[s] whether the plaintiff has pleaded factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." In so doing, the court "accept[s] as true all well-pleaded factual allegations in the complaint,

[1] Despite diligent efforts, Defendants can find no case to date in which a federal court fully analyzed whether the FTC's substantiation scheme was a proper statutory interpretation. In *F.T.C. v. Garvey*, 383 F.3d 891, 903-904 (9th Cir. 2004), decided pre-*Loper*, the 9th Circuit stressed that a court considering an enforcement case based on FTC substantiation guidance should not extend *Chevron* deference, but would need to determine the degree of deference the action should otherwise be accorded. However, the 9th Circuit threw out the FTC's case without addressing the issue of deference and the permissibility of the substantiation scheme.

> resolve[s] all reasonable inferences in the plaintiff's favor, and ask[s] whether it is plausible that the plaintiff is entitled to relief." Further, the court rejects "mere labels and legal conclusions" offered by the plaintiff.[2]

ARGUMENT

I. THE COMPLAINT SEEKS RELIEF BEYOND WHAT THE PLAIN LANGUAGE OF THE FTC ACT PROHIBITS

The Commission's claims fail because they do not allege that Defendants engaged in any conduct that violated the plain language of the FTC Act. Put another way, none of Defendants' alleged conduct falls within the FTC Act's enumerated prerequisite actions that can trigger liability. Because the Complaint fails to allege that Defendants engaged in conduct that in any way violates the plain language of the FTC Act, the Commission's claims fail as a matter of law and should be dismissed with prejudice.

A. The Complaint Does Not Allege that Defendants Engaged in Any "Deceptive Acts or Practices" That Could Violate the Act

On its face, the plain language of the applicable statutes—the starting point for any proper legal analysis as set forth below—does not apply to Defendants' purportedly unlawful acts. The two claims in the Complaint invoke two statutes: Sections 5(a) and 12 of the FTC Act and the COVID-19 Consumer Protection Act, but the analysis hinges on the language of the FTC Act.[3] Section 12 of the FTC Act prohibits the dissemination of false advertisements "in or affecting commerce" with respect to "food, drugs, devices, services or cosmetics." Specifically,

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[2] *Dunham v. Saratoga Springs City*, Case No. 2:19-cv-00641, 2020 WL 5057606, *2 (D. Utah, Aug. 27, 2020) (cleaned up and footnotes omitted).

[3] The COVID-19 Consumer Protection Act provides that any act or practice that "is associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19" that is itself a "violation of Section 5(a) of the FTC Act" is also a violation of the COVID-19 Act. Complaint, ¶ 15. Thus, if an act or practice does not violate the FTC Act, it does not constitute a violation of the COVID-19 Act.

section 5(a) of the FTC Act renders "unlawful" "unfair[4] or deceptive acts or practices in or affecting commerce."[5] Significantly, the Complaint does not allege that Defendants have engaged in any "unfair" acts. Thus, the Complaint's causes of action rise or fall based solely on whether Defendants' alleged conduct constitutes "deceptive acts or practices."

Fatally, the Complaint fails to allege any facts that constitute "deceptive acts or practices" within the plain meaning of the statute. Instead, the Complaint's allegations are based on the Commission's self-created standard that is wholly absent from the statutory text. Nowhere do any allegations set forth facts demonstrating that Defendants actually made any false, misleading or deceptive statements. Instead, the Commission's claims are based on what it contends are "false or misleading, *or unsubstantiated* representations that Xlear nasal spray products are effective for the treatment or prevention of COVID-19."[6] Reading the Complaint further, rather than setting forth any false or misleading statements, the Complaint alleges that Defendants made statements that are "unsubstantiated." Defendants' statements regarding Xlear nasal spray are allegedly "unsubstantiated" because, according to the Complaint, Defendants purportedly lack "competent and reliable scientific evidence" to support their statements.

Nowhere does the FTC Act require Defendants to possess this precise form—or *any form*—of substantiation in support of its statements. In making these allegations, the Commission merely relies on a self-determined, extra-statutory standard it has created by agency fiat. Further, the Complaint alleges that the specific factual reason that Defendants lack this

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[4] Although not applicable to the allegations of the Complaint, the statute clarifies that an act is "unfair" if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. Sec. 45(n). It should further be noted that the complaint does not provide allegations supported by facts as to any substantial injury.

[5] 15 U.S.C. Sec. 45(a)(1).

[6] Complaint ¶¶ 40, 45 (emphasis added).

purportedly-required substantiation is that Defendants do not rely on product-specific, "randomized clinical trials." According to the Commission—but again nowhere in the statute—the lack of such clinical trials is enough to trigger liability under the statute and carry the Commission's burden of proof in this case.

Paragraphs 19 through 22 of the Complaint lay out the Commission's principal allegations of "Defendants' Unlawful Conduct":

> 19. Since at least March 2020, Defendants have advertised and promoted Xlear nasal spray for the prevention and treatment of COVID-19. Defendants have used tools like magazine advertorials, You Tube videos, social media posts, and websites like xlear.com to disseminate their claims to consumers nationwide.
>
> 20. ***There is no competent and reliable scientific evidence that Xlear nasal spray treats or prevents COVID-19. At present, no published reports of randomized clinical trials establish the use of Xlear nasal spray as effective in preventing or treating COVID-19.***
>
> 21. ***Despite this lack of evidence***, Defendants have made numerous claims that explicitly or implicitly state that daily use of Xlear nasal spray is effective in treating or preventing COVID-19. . .
>
> 22. ***Defendants lack any competent and reliable scientific evidence to support the foregoing claims*** and other similar statements they have disseminated or caused to be disseminated regarding Xlear nasal spray's use in treating or preventing COVID-19. [7]

Importantly, the Commission does not allege that such statements are false, or that they are

[7] Complaint, ¶¶ 19-22 (emphasis added). The allegations in Count Two (for violations of the COVID-19 Consumer Protection Act) suffer from the same infirmities. There, the Complaint identifies three statements the Commission contends Defendants have made, "directly or indirectly, expressly or by implication," which allegedly "are false, misleading, or were not substantiated at the time the representations were made." Complaint ¶¶ 46-47. But the Complaint is devoid of any *facts* that would support the *conclusory claim* that the statements are "false or misleading." *See* Bryan v. Stillwater Bd. of Realtors, 578 F.2d 1319, 1321 (10th Cir. 1977) ("On a motion to dismiss, facts well pleaded are taken as correct, but allegations of conclusions or of opinions are not sufficient when no facts are alleged by way of the statement of the claim."). In any event, acts or practices are actionable under the COVID-19 Act only if they are independently violative of the FTC Act. Where the only basis alleged for violations of the FTC Act is a purported lack of substantiation, that is the only basis on which violations of the COVID-19 Act could rest.

deceptive for any reason other than being unsubstantiated by "competent and reliable scientific evidence." Indeed, the phrasing of these allegations demonstrates that even the Commission recognizes that "not substantiated" is something different than "false or misleading," yet the FTC Act on its face bars only acts that are "deceptive," or, in Section 12, "false." While plainly the Commission believes that "false", "deceptive" and "unsubstantiated" are synonymous, the statute says no such thing.

B. The FTC Act is Clear on its Face: It Does Not Mention—Let Alone Prohibit—Statements that are Merely "Unsubstantiated"

As noted, in analyzing whether the Complaint alleges conduct that is actionable under the statute, the Court must begin by looking to the face of the law at issue.[8] The proper inquiry is not what *the Commission* believes the law to be, but rather what the statute says. "[The court's] goal is to 'ascertain the congressional intent and give effect to the legislative will.'"[9] We first examine the statute's plain text. *Id.* (citation omitted). Absent ambiguity, our analysis ends there."[10]

Moreover, as the Supreme Court has recently reaffirmed, the singular goal of statutory interpretation is to discern the statute's "single, best meaning. That is the whole point of having written statutes: 'every statute's meaning is ***fixed at the time of enactment***.'"[11] Thus, the ultimate question is whether the FTC Act, **at the time of its enactment** and any relevant amendments, means what the Commission says it does. As *Loper* explained, "[I]t thus remains

[8] *King v. Burwell*, 576 U.S. 473, 486 (2015) ("If the statutory language is plain, we must enforce it according to its terms.").
[9] *In re Taylor*, 899 F.3d 1126, 1129 (10th Cir. 2018) (citation omitted).
[10] *United States v. Koerber*, 10 F.4th 1083, 1112 (10th Cir. 2020).
[11] *Loper*, 144 S. Ct. at 2266 (quoting *Wisconsin Central Ltd. v. United States*, 585 U.S. 274, 284) (emphasis added).

the responsibility of the court to decide whether the law means what the agency says."[12] Here, the Commission's claims hinge on words and interpretation that go far beyond the plain language of the FTC Act.

> The starting point, as always, is the plain language of the FTC Act:
>
> As the Supreme Court has noted, the legislative purpose generally is expressed in the ordinary meaning of the words Congress has used. *United States v. Locke*, 471 U.S. 84, 95, 105 S. Ct. 1785, 85 L. Ed. 2d 64 (1985); *see Burlington N. R.R. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461, 107 S. Ct. 1855, 95 L. Ed. 2d 404 (1987). The most fundamental guide to statutory construction is common sense. *First Methodist Church v. United States Gypsum Co.*, 882 F.2d 862, 869 (4th Cir. 1989), *cert. denied*, 493 U.S. 1070, 110 S. Ct. 1113, 107 L. Ed. 2d 1020 (1990).[13]

Here, the pertinent provisions of the FTC Act—specifically, sections 5(a) and 12, codified at 15 U.S.C. §§ 45(a) and 52—have remained largely unaltered since they were enacted by Congress and signed into law on September 26, 1914—a period of 110 years.[14]

The question, then, is simple: does the plain language of the FTC Act, when given its "common sense" meaning "at the time of enactment," bar advertising claims—including claims that may be objectively true--merely because they are "unsubstantiated"? The answer is unequivocally no, which should end the analysis—and bring an end to the Commission's claims. Indeed, the relevant language in the FTC Act is not ambiguous:

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[12] *Loper*, 144 S. Ct. at 2261 (cleaned up). *See also FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 385 (1965) ("in the last analysis the words 'deceptive practices' set forth a legal standard and they must get their final meaning from judicial construction.").

[13] *Salt Lake City v. Western Area Power Admin.*, 926 F.2d 974, 984 (10th Cir. 1991) (Tacha, J., dissenting).

[14] Sections 5 and 12 were both amended in 1938 to include "unfair" acts or practices within the scope of the statutory prohibitions. As noted, the Commission has not here alleged that Defendants engaged in any "unfair" acts—only deceptive ones. Moreover, the Commission had not alleged that it has considered any of the elements it is required by statute to assess before declaring an act or practice "unfair"—specifically, whether the act is likely to cause "substantial injury," whether the injury is "reasonably avoidable by consumers themselves," and whether the injury "is outweighed by counterveiling benefits to consumers or to competition." 15 USC § 45(n).

> In determining whether statutory language is ambiguous, we look to "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Keller Tank Servs. II v. Comm'r*, 854 F.3d 1178, 1196 (10th Cir. 2017) (quotation omitted). A statute is ambiguous if it, "is capable of being understood by reasonably well-informed persons in two or more different senses." *Allen v. Geneva Steel Co. (In re Geneva Steel Co.)*, 281 F.3d 1173, 1178 (10th Cir. 2002).[15]

Thus, the threshold question is whether the phrase "deceptive acts or practices" can be "understood by reasonably well-informed persons" to mean "every unsubstantiated claim," including claims that may be true.

The plain language of the FTC Act, from its enactment in 1914 through the present day, has barred "deceptive acts or practices," but has never even mentioned let alone required substantiation as a prerequisite to making claims.[16] On this precise point the Seventh Circuit Court of Appeals in *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2008), held:

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand.[17]

It is not as though the concept of advertisers making claims that may or may not be substantiated was unheard of in 1914, or in 1938 when the FTC Act was amended. Indeed, given that nearly every advertising claim makes an assertion about the product or service being offered that could be, in some way, "substantiated," the idea that Congress, when barring "deceptive acts or practices," intended to require every advertiser to possess substantiation before making such claims is simply not compatible with "common sense."[18] "And it is normal usage that, in the

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[15] *William F. Sandoval Irrevocable Trust v. Taylor (In re Taylor)*, 899 F.3d 1126, 1129 (10th Cir. 2018).
[16] *See, e.g.*, 15 U.S.C. § 45(a).
[17] *Id.* (discussing FTC's substantiation by RCT interpretation).
[18] *Cf. Id.* at 861 ("Think about the seller of an adhesive bandage. . . .The seller does not need to conduct tests before asserting that this product reduces the risk of infection . . . .).

absence of contrary indication, governs our interpretation of texts."[19] Nothing in the "normal usage" of the terms "false" and "deceptive," particularly at the time the FTC Act or its relevant amendments became law, supports the Commission's views that every "unsubstantiated" claim violates the FTC Act, and that every statement—even inherently true ones—must possess substantiation. Simply put, it's just not in the law.

Nor can the relevant language of the FTC Act be deemed ambiguous—that is, a "reasonably well-informed person" simply could not read a bar on "deceptive acts or practices" to require "every advertising claim that is unsubstantiated." Because the plain language of the statute, read in a common-sense manner, does not include or support any "substantiation" requirement, the statutory analysis should end there. And because the claims the Commission asserts in the Complaint presuppose that the statute requires some kind of substantiation, the claims go beyond what the statute supports and should be dismissed.

II. EVEN IF SOMEHOW AMBIGUOUS, THE "BEST READING" OF THE FTC ACT DOES NOT SUPPORT THE COMMISSION'S BLANKET PROHIBITION ON ALL UNSUBSTANTIATED CLAIMS

Even if the Court were to determine the plain language of the relevant provisions of the FTC Act was somehow ambiguous, the "best reading" of the FTC Act does not support a reading in which "false" or "deceptive" is equivalent to "unsubstantiated." Application of the traditional "canons" of statutory construction only bolster the conclusion that Section 5 of the FTC Act does not bar all unsubstantiated claims. This subsection discusses the most relevant canons and explains why their application in this case compels dismissal.

[19] *Freeman v. Quicken Loans, Inc.*, 566 U.S. 624 (2012).

A. The Words "Substantiation" and "Unsubstantiated" Do Not Appear in the FTC Act

The first and most obvious reason against manufacturing substantiation into the meaning of the FTC Act is that the word simply does not appear there. Neither do any of its derivatives or synonyms. The concept of whether a claim is substantiated is different from whether it is false or deceptive. Not all claims that lack substantiation are false or deceptive. Indeed, it is widely acknowledged, from both a scientific and common-sense standpoint, that claims can be (a) true but unsubstantiated, and (b) false but substantiated. History and science books are full of examples of theories that had been substantiated and believed for decades, even millennia, that we now know are false (e.g., the theory that the sun revolved around the Earth).[20] And vice versa (e.g., the efficacy of a parachute, while not substantiated, is nonetheless indisputably true.).[21, 22]

B. Congress Could Have Included the Word "Substantiation" in the FTC Act But Has Not Done So

If the FTC Act nowhere specifically requires substantiation, *a fortiori* it does not require

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[20] Even Plaintiff's own's witnesses acknowledge such facts in their deposition testimony. For example, Christine DeLorme (an attorney in the advertising practices section of the FTC) testified: "That is correct. Something could be actually true, but not substantiated." DeLorme Dep. at 79:4-7. And, in response to the question "[a]nd the opposite is also true. Something could be substantiated but not true", Ms. DeLorme testified "Correct. Sometimes science turns out to be incorrect." *Id.* at 79:8-11. Defendants recognize that Ms. Delorme's testimony is outside the pleadings and cannot provide a basis for the Court to grant this Motion. Defendants simply refer to her testimony to demonstrate the common sense nature of these fundamental and, frankly universally accepted, principles.

[21] *See, e.g.*, Serious Problems With RCTs And EBTs Exposed By The Satirical 'Parachute Study', Forbes, Dec. 30, 2018, available at https://www.forbes.com/sites/toddessig/2018/12/30/serious-problems-with-rcts-and-ebts-exposed-by-the-satirical-parachute-study/?sh=3d0f5ce853f2.

[22] Moreover, at any rate "[u]nanimity of opinion in the scientific community, on virtually any scientific question ... is extremely rare." *Basic Research., LLC v. Federal Trade Comm'n*, Case No. 2:09-cv-0779, 2014 WL 12596497, at *10 (D. Utah Nov. 25, 2014) (quoting *United States v. Williams*, 583 F.2d 1194, 1198 (2d Cir. 1978)). This further demonstrates the faulty reasoning with the Commission's self-created substantiation requirement and why the statute should not be read to include it.

the specific type of substantiation on which the Commission's allegations hinge. Had Congress wanted to include the concept that every unsubstantiated claim is inherently "deceptive," it could have included such language, either at the statute's enactment or by subsequent amendment. It has never done so. This is no oversight. Congress is aware of the issue and knows how to impose a substantiation requirement where desired, as it has expressly done so for a specific subset of products at issue in the FDA Act. For example, in 1994, Congress passed the Dietary Supplement Health and Education Act of 1994, portions of which significantly amended 21 USC § 343 – the "Misbranded Food" section of the FDA Act. Of particular relevance here was the addition of subsection r(6), which stated, in pertinent part: "For purposes of paragraph r(1)(B), a statement for a dietary supplement may be made if— . . . (B) ***the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading*** . . . ."[23] Critically, Congress has never amended the FTC Act to include similar language.

Significantly, the FDA Act had, since its original enactment in 1938, always barred "false or misleading" labeling of food products.[24] If Congress understood and expected that claim substantiation was required *in all instances* to make claims "truthful and not misleading," there would have been no need to add specific statutory language requiring substantiation for a tiny subset of food claims—specifically, those made by manufacturers of dietary supplements. Imposing a specific requirement on one small subset of manufacturers necessarily implies that other manufacturers are not subject to this additional restriction. Moreover, the addition of a provision requiring such substantiation for dietary supplement manufacturers can only be understood as a tacit acknowledgement that no such requirement existed in the statute before it

[23] 21 U.S.C. § 343(r)(6) (emphasis added).
[24] 21 U.S.C. §343(a).

was amended. Reaching any other conclusion would do violence to the "cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant."[25]

Indeed, if the FDA Act had already provided that all manufacturers of food products had to have substantiation in order to make claims, the 1994 amendment referenced above would have itself been entirely superfluous. Going further, if, as the Commission contends, the FTC Act truly required every manufacturer of every product to possess substantiation before making any objective claim, then the inclusion of such a requirement in the FDA Act specific to dietary supplement manufacturers was entirely redundant. Likewise, if Congress believed in 1994 that a substantiation requirement should be imposed on all product manufacturers, it would have made far more sense for Congress to amend the FTC Act to so state, rather than impose the requirement on a miniscule subset of product marketers.[26]

In sum, the language of the FTC Act does not support a "best reading" that would prohibit all unsubstantiated claims—including those that are true—and subsequent congressional action demonstrates the absurdity of reading the FTC Act to impose such a standard. The plain language of the FTC Act—which says nothing of substantiation—should be followed and the Commission's claims dismissed.

C. The Commission's Interpretation Engenders Constitutional Questions

The Commission's interpretation of the FTC Act should further be rejected as not "best" because it violates the maxim "to avoid an interpretation of a federal statute that engenders

[25] *TRW Inc. v. Andrews*, 534 U.S. 19, 31 (2001).

[26] Although there is no readily available data as to the size of the supplement market in the United States in 1994, there is good data setting the value at about $4.3 billion in 2002. In that same year the total United States GDP was about $10.6 trillion, meaning that the supplement market made up 0.004 percent of the total US economy.

constitutional issues if a reasonable alternative interpretation poses no constitutional question."[27]

1. The FTC's Interpretation Violates the First Amendment

Interpreting the FTC Act to bar all claims that are not substantiated, whether or not those claims are true, plainly implicates serious First Amendment concerns.[28] That the messages at issue relate to the sale of a product does not devoid the messages of First Amendment protection. The Supreme Court has long held that "speech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another. Speech likewise is protected even though it is carried in a form that is 'sold' for profit, and even though it may involve a solicitation to purchase or otherwise pay or contribute money."[29]

Here, the Commission's censorship is content-based. And, the statements that the Commission seeks to censor go beyond the mere solicitation of a commercial transaction. They sought to educate the public about ways to fight a global pandemic—one that at the time the statements were made had no cure or vaccine.[30] Indeed, in those uncertain times, even the United

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[27] *Gomez v. United States*, 490 U.S. 858, 864 (1989).

[28] As explained below, the Commission actually contends (and pleads) that claims are prohibited unless they are substantiated by randomized clinical trials. That is an inherently absurd proposition, particularly where highly respected members of the scientific community recognize that there are many claims that simply cannot be tested using randomized clinical trials. A comical but useful example often cited in scientific literature is the proposition that parachutes save lives. No one has—or, presumably, would ever—conducted a randomized clinical trial to prove the point, because doing so would require half the study participants to be dropped from airplanes without parachutes. Yet, using the standard and interpretation advocated by the Commission, anyone marketing parachutes without having conducted randomized clinical trials could make no claim regarding their ability to save lives and could be punished and enjoined under the FTC Act.

[29] *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 761 (1976).

[30] For example, one of the claims the Commission directly challenges in its Complaint is: "With the pandemic raging worldwide, we must use every tool we can to fight it. . . . Weighing our 20-year safety record, against the risks of this deadly virus, it's clear Xlear needs to be in widespread use." Complaint [ECF No. 2], ¶ 21(c).

States government gave conflicting advice (e.g., first stating that washing produce would protect and then later reversing that position; first stating masks didn't help, then reversing that position). Defendants' speech offering potential solutions, even though mixed with speech connected with the sale of a product, is entitled to the highest levels of protection afforded speech under the First Amendment.[31]

Under that test, applying the Supreme Court's strict scrutiny standard, the Commission's interest in protecting the public from misinformation can only pass constitutional muster if its position that Defendants' statements can only be made if backed by the results of a clinical trial is "not more extensive than is necessary to serve that interest."[32] The Commission's position fails because the Commission's "interest could be served by an alternative that is less restrictive of speech."[33] Requiring that all statements concerning a product be backed by clinical trials is not realistic and unduly restrictive.

Moreover, even if Defendants' statements were deemed pure commercial speech and thus entitled to only an intermediate level of constitutional scrutiny, the Commission's desired restriction still fails. In the seminal *Central Hudson* case, the Supreme Court explained how the State (and Congress) can justify limitations on commercial speech:

> If the communication is neither misleading nor related to unlawful activity, the government's power is more circumscribed. The State must assert a substantial interest to be achieved by restrictions on commercial speech. Moreover, the regulatory technique must be in proportion to that interest. The limitation on

[31] *See, e.g.*, *Riley v. Nat'l Fed'n of the Blind of N. Carolina, Inc.*, 487 U.S. 781, 796 (1988) ("Where . . . component parts of a single speech are inextricably intertwined, we cannot parcel out the speech, applying one test to one phrase and another test to another phrase. Such an endeavor would be both artificial and impractical. Therefore, we apply our test for fully protected expression."); *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 81 (1983) (Stevens, J. concurring) ("advertisements may be complex mixtures of commercial and noncommercial elements").

[32] *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 554 (2001).

[33] *Id.* at 582 (Thomas, J. concurring).

> expression must be designed carefully to achieve the State's goal. Compliance with this requirement may be measured by two criteria. First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.[34]

A reading of the FTC Act that prohibits every unsubstantiated claim on every product, regardless of whether the claim is true, and irrespective of the type of product at issue or the circumstances presented, is overbroad and cannot survive Constitutional scrutiny.

Moreover, the *Central Hudson* analysis reiterates that commercial speech that is "misleading" is treated differently than speech that is not. And the Government always bears the burden of proving speech is misleading before it can be regulated; there is no circumstance in which the Government can shift its burden of proof and make the speaker prove its speech is true or not misleading—at least not until the Government has first met its burden of proving otherwise.[35] Yet accepting the Commission's interpretation of the FTC Act—that all claims are misleading unless substantiated—plainly shifts the burden of proof to Defendants, the speaker, to prove that their claims are substantiated. The Commission would effectively urge that it satisfies its burden of persuasion merely by alleging that someone spoke; the onus would then be on the speaker to prove the speech was substantiated.

2. The FTC's Interpretation Violates the Equal Protection Clause

The Commission's attempt to create a substantiation requirement improperly shifts its burden of persuasion onto Defendants in violation of the Equal Protection Clause. It is axiomatic

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[34] *Central Hudson Gas & Elec. Corp. v. Public Svc. Cmm'n*, 447 U.S. 557, 564 (1980).
[35] *See, e.g.*, *Alliance for Natural Health US v. Sebelius*, 786 F. Supp. 2d 1, 13 (D.D.C. 2011) (*"*But if the speech is lawful and not misleading, or is only potentially misleading, the Court must" undertake the *Central Hudson* analysis).

that the plaintiff in any lawsuit generally bears the burden of proving its claims.[36] In *Director, OWCP v. Greenwich Collieries*, the Supreme Court held that without a specific statutory authorization an agency cannot shift the burden of proof in enforcement cases on to Defendants.[37] Whether stated or not, an obvious purpose behind the Commission's adoption of a substantiation requirement is to shift the burden of proving a violation of the FTC Act off of the Commission and compel the Defendants to prove they did not violate the law. This would be akin to a prosecutor charging a defendant guilty of a crime not because evidence proved it, but solely because the defendant allegedly lacked an alibi.

According to the Commission, the Commission need only make an allegation that the Defendants lacked substantiation and then compel the Defendants to prove they did not violate the FTC Act.[38] In other words, under the Commission's "competent and reliable scientific evidence" scheme, if the Commission offers only evidence that a claim was made and a bald contention that it was not substantiated, but offers no evidence of a violation of the actual

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[36] *See, e.g.*, *National Council Against Health Fraud, Inc. v. King Bio Pharmaceuticals, Inc.*, 107 Cal. App. 4th 1336, 1344 (Cal. App. 2003) ("a plaintiff in a false advertising or unlawful competition action has the burden of producing evidence that the challenged advertising claim is false or misleading.").

[37] 512 U.S. 267, 281 (1994). *Greenwich Collieries* was an Administrative Procedures Act (APA) challenge. However, the APA simply adopts the "customary", "standard" rule as to burdens of persuasion in enforcement cases. S. REP. NO. 79-752, reprinted in STAFF OF S. COMM. ON THE JUDICIARY, 79TH CONG., ADMINISTRATIVE PROCEDURE ACT—LEGISLATIVE HISTORY 1944–46, S. DOC. NO. 248, at 185, 228 (1946). It is logical that the same customary standard applies equally when an agency seeks to circumvent the APA by issuing mere guidance and not a rule—as the Commission did here.

[38] *See, e.g.*, *Basic Research, LLC v. Fed. Trade Comm'n,* Case No. 2:09-cv-0779 CW, 2014 WL 12596497, *8 (D. Utah Nov. 25, 2014) (FTC must make a prima facie case before shifting the burden on to the defendant to show substantiation); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged."). *See also* Blacks Law Dict., (9th ed. 2009) (Prima facie means "At first sight; on the first appearance; on the face of it; so far as can be judged from the first disclosure; presumably.").

statutory provision (that is, that the claim is false or deceptive), the Commission will prevail unless Defendants prove they had substantiation that the Commission deems adequate. This is improper under *Greenwich Collieries* because Congress has never authorized the Commission to shift the burden of proof in actions seeking civil penalties.

D. The History of Sections 5 and 12 of the FTC Act Shows Congress Could Not Have Intended to Require Substantiation

Section 5 of the FTC Act was enacted in 1914, while Section 12 was enacted in 1938. At that time, clinical substantiation was not in a widespread scientific parlance, let alone practice. The very first double-blind study (Patulin for colds) didn't occur until 1943, the first randomized controlled trial of streptomycin did not occur until 1946.[39] According to the FDA, modern clinical trials (substantiation in FTC terms) did not become a part of evidence-based medicine in the United States until after World War II.[40] It is implausible to suggest Congress intended the FTC Act to authorize a then-nonexistent scientific principal.

E. The History of Interpretation and Enforcement of the FTC Act Does Not Support the Commission's Position That All Unsubstantiated Product Claims Are Actionable

The history of the FTC Act and its enforcement further supports rejection of the Commission's extra-statutory interpretation. For the sixty years following enactment of the FTC Act, nothing in either the legislative history of the FTC Act or its interpretation by the

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[39] *See* Bhatt A. Evolution of clinical research: a history before and beyond james lind. Perspect Clin Res. 2010 Jan;1(1):6-10. PMID: 21829774; PMCID: PMC3149409.

[40] *See* FDA, FDA and Clinical Trials: A Short History, undated, at 2, available at https://www.fda.gov/media/110437/download. Clinical testing (substantiation in effect) even of new drugs was not required until the 1938 Food, Drug and Cosmetic Act. FDA Clinical Trials, supra, at 5. Even then, there was no actual requirement that such data be submitted, only that sponsors had to demonstrate they had done reasonable testing to determine safety. *Id*. Interestingly, this vague FDA testing requirement was enacted by the same Congress that passed the FTC Act sections 5 and 12 amendments. Which is to say, if that same Congress intended to require testing and substantiation under the FTC Act, it knew how to do it and did not.]

Commission itself and the courts supports a reading that "deceptive" or "false" means "unsubstantiated," let alone "unsubstantiated by competent and reliable scientific evidence."

As set forth in *Loper*, courts may, in some cases, "seek aid from the interpretations of those responsible for implementing particular statutes," and that "interpretations issued contemporaneously with the statute at issue, and which have remained consistent over time, may be especially useful in determining the statute's meaning."[41] That history is illuminating here because: (1) the Commission did not purport to require or even discuss substantiation during the first sixty years that the FTC Act was law; (2) when the Commission issued its decision in *Pfizer* which, for the first time imposed a "reasonable basis" substantiation standards in the context of a specific case, it did not ground its ruling in any kind of statutory analysis; and (3) for years thereafter, the Commission itself did not believe, or argue in any court, that the FTC Act allowed it to prosecute violations based merely on the absence of substantiation.

1. 1914 through 1971

If the plain language of the FTC Act's prohibition on "deceptive acts or practices" were intended or understood to mean "any claim that is not substantiated," there is no evidence of this in the first *sixty years* of the statute's existence. Defendants' counsel has not found a single case or administrative proceeding before 1972 in which the Commission—or anyone else, for that matter—took the position that advertising claims were even arguably deceptive, let alone *deceptive as a matter of law*, simply because the claims were unsubstantiated. Thus, the "best reading" of the statute cannot be one that imposes a *per se* bar on unsubstantiated claims, because no one—not Congress nor the Commission—gave it that reading during the first sixty years of its existence.

[41] *Loper*, 144 S.Ct. at 2262.

2. In 1972, FTC Administrative Case, Pfizer, Introduced a Substantiation Requirement Without Statutory Justification and While Relying On Weak Precedent

The origin of the Commission's position that a marketer must have a "reasonable basis" for its claims can be traced—not to any statutory analysis by a court—but directly to the Commission itself. By all appearances, the "reasonable basis" theory originated in the Commission's decision in *In Re Pfizer Inc.*, 81 F.T.C. 23 (July 11, 1972). And there is no doubt that its invention was purely a creature of the Commission's own views—not those of any court, let alone the Congress that enacted the statute: "Turning to that part of the complaint which challenges respondent's marketing practices as unfair, ***the Commission is of the view that it is an unfair practice in violation of the Federal Trade Commission Act to make an affirmative product claim without a reasonable basis for making that claim***."[42]

Making matters worse, the Commission's view, which led to a revolution in the way it prosecuted alleged violations of the FTC Act, hinged on a case that does not support its position. The only case relied on or cited by the Commission in *Pfizer* was *Tashof v. FTC*, 437 F.2d 707 (D.C. Cir. 1970). Significantly, the *Tashof* Court merely affirmed a remedial order—following a determination by the Commission that the respondent had engaged in deceptive and unfair advertising—requiring the respondent to take a survey of comparative prices before making future claims that its products were discounted.[43] And that context—the review of the *remedy* for proven false advertising, not the basis for a deceptive advertising claim—was central to the court's holding and analysis. The *Tashof* court noted: "The Commission claims that this remedy constitutes reasonable action calculated to preclude revival of the illegal practices. We agree. . . .

[42] *Id.* at *29 (emphasis added).
[43] The *Tashof* court discussed four kinds of deception that had been proven in the administrative proceeding, not one of which was making unsubstantiated claims. *Id.* at 709.

Where a businessman has wrought a wrong on the public, he may be held to a reasonable business procedure that will prevent repetition of that wrong . . ."[44]

As will be explained more fully below, the imposition of substantiation requirements in connection with remedial orders, or "fencing in" provisions as they have been commonly known, does nothing to support the idea that the FTC can shift the burden of proof to the respondent in the first instance—*before any wrongdoing has been proven*. Indeed, these restraints on commercial speech were only justified as a response to proven wrongdoing. This suggests, by negative implication, that the government may not impose a burden of proof on a commercial speaker before the speaker has been adjudicated to have broken the law. Yet the exceptionally limited holding in *Tashof*, in a very specific context, was the lone case authority invoked by the Commission to support its sweeping and unilateral change in the law, allowing it to satisfy its burden of proof by pointing to an absence of evidence that it deemed would provide "a reasonable basis" for challenged claims.[45]

Unfortunately, *Pfizer* became the flimsy foundation on which the Commission has often relied when justifying this tectonic shift in how it sought to establish violations of the FTC Act. Of course, if the words "unfair or deceptive acts and practices" were meant at the time they were

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[44] *Id.* at 715. It is also noteworthy that one of the three judges on the appellate panel in *Tashof* dissented, explaining: "In my judgment the Commission exceeds its authority when it requires [the respondent] to conduct a 'statistically significant survey' of relevant prices in its trade area before advertising a 'discount price'. **This requirement shifts the burden to [respondent] of proving its innocence; and as the majority opinion concedes, might subject [respondent] to heavy civil penalties even if its advertising is true.** I would affirm after eliminating this part of the order." *Id.* at 715-716 (Judge Robb, Dissenting) (emphasis added). Defendants discussed above the impropriety of reading the FTC Act in a manner that would allow the Commission to shift the burden of proof to the Defendants.

[45] *See Pfizer* at *30 ("In summary, the Commission concludes that the making of an affirmative product claim in advertising is unfair to consumers unless there is a reasonable basis for making that claim.").

written and enacted to include the sweeping category of claims that are made without a reasonable basis, the obvious question is why no court so held, and why the Commission itself offered no such interpretation, for more than half a century after the FTC was enacted. But the Commission itself never even suggested that its conclusion is *Pfizer* was based in any way on the language of the statute. It wasn't.

Moreover, the fact that the Commission in *Pfizer* grounded its decision in the "unfairness" prong of the FTC Act, rather than the "deceptive" prong, is significant. It has been well-documented that the Commission took a hyper-aggressive approach to its regulation of "unfair" trade practices in the 1970's—the very time period when *Pfizer* was decided.[46] The Commission's overreach in the 1970's and 1980's led to Congressional action in 1994, when the FTC Act was amended to codify certain express limitations on the Commission's power to declare business practices "unfair." Specifically, the 1994 amendment inserted subsection (n) into 15 U.S.C. § 45, providing:

> The Commission shall have no authority under this section or section 18 to declare unlawful an act or practice on the grounds that such act or practice is unfair unless the act or practice causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. In determining whether an act or practice is unfair, the Commission may consider established public policies as evidence to be considered with all other evidence. Such public policy considerations may not serve as a primary basis for such determination.

If the Commission has decided that the cost of unsubstantiated claims always outweighs the benefit, even if the statements at issue are true, then the Commission is simply ignoring the

[46] *See, e.g.*, "The FTC's Use of Unfairness Authority: Its Rise, Fall, and Resurrection," by J. Howard Beales (Former Director of the FTC's Bureau of Consumer Protection), available on the FTC's website: https://www.ftc.gov/news-events/news/speeches/ftcs-use-unfairness-authority-its-rise-fall-resurrection#N_17_.

statute. In this instant case, for example, before it could even purport to make an "unfairness" determination, under subsection (n) the Commission would first have to evaluate the potential risks and rewards to consumers of using a product that might (a) lower their risk of a COVID-19 infection, and/or (2) decrease the severity and length of their COVID-19 symptoms, and the risks posed by denying consumers of information that the Commission has not, cannot, and will not prove is false. Likewise, the Commission would need to undertake an evaluation of what potential benefits are lost if consumers cannot make their own choices as to what to buy and use, particularly in the context of a global pandemic when everyone was telling people there was nothing they could do. The Commission does not even purport to have undertaken this or any other analysis; it cannot simply eschew the cost/benefit calculation, yet it is never even mentioned in the Complaint. The Complaint thus fails to state valid claims even under the Commission's own purported standard.

3. The Subsequent "Fencing In" Jurisprudence Cannot Justify Blanket Imposition of the Commission's Extra-Statutory Substantiation Requirement

Cases decided since *Pfizer*, even those that impose a substantiation requirement, do not support imposition of any requirement to show substantiation absent an initial finding of false or deceptive marketing. In a series of cases beginning in the late 1970's—nearly a decade after *Pfizer*—the Commission was forced to defend its imposition of a substantiation requirement *on parties who had already been determined to have made false or misleading claims* in their advertising. These so-called "fencing in" provisions in FTC orders were upheld by courts, but only because the Commission was given greater leeway with those who had already been adjudicated (or were admitted) lawbreakers. By that time, the United States Supreme Court had already blessed the use of such provisions—but only in that limited context:

> Orders of the Federal Trade Commission are not intended to impose criminal punishment or exact compensatory damages for past acts, but to prevent illegal practices in the future. In carrying out this function the Commission is not limited to prohibiting ***the illegal practice in the precise form in which it is found to have existed in the past***. If the Commission is to attain the objectives Congress envisioned, it cannot be required to confine its road block to the narrow lane ***the transgressor*** has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity.[47]

Thus, the entire premise of a "fencing in" order was that it applied only to a proven "transgressor," and only where an "illegal practice" has been "found to have existed in the past."

For example, when the Second Circuit in *Jay Norris, Inc. v. FTC* affirmed imposition of an order requiring substantiation, and largely dodged any First Amendment arguments, it was careful to make clear: "we hold only that because the FTC here imposes the requirement of prior substantiation ***as a reasonable remedy for past violations of the FTC Act***, there is no unconstitutional prior restraint of petitioners' protected speech."[48] Similar results are found in other Circuit Court cases in the late 1970's and early 1980's, all following the same logic—that a substantiation requirement could be imposed *as part of a remedial order after* the respondent had been found to have engaged in false or misleading advertising.[49]

In *Porter & Dietsch, Inc. v. FTC*, 605 F.2d 294 (7th Cir. 1979), the Seventh Circuit directly addressed an argument that the imposition of a substantiation requirement as part of a remedial order "improperly relieves the Commission of the burden of proving their advertising

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[47] *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952) (emphasis added); *see also FTC v. National Lead Co..*, 352 U.S. 419, 431 (1957) ("respondents must remember that those caught violating the [FTC] Act must expect some fencing in.").

[48] *Jay Norris, Inc. v. Federal Trade Com.*, 598 F.2d 1244, 1252 (2d Cir. 1979) (emphasis added).

[49] *See, e.g.*, *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 220 (2d Cir. 1976) (affirming remedial order prohibiting defendant from making marketing claims similar to those that were proven to be deceptive unless the claims "can be substantiated"); *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 389 (9th Cir. 1982) (affirming remedial order requiring "a reasonable basis . . . which shall consist of competent and reliable tests, or other competent and reliable evidence which substantiates" advertising claims before such claims are made).

representations false and imposes on petitioners the burden of proving the truthfulness of the claims they make."[50] Notably, "the Commission defend[ed]" that requirement, *not by arguing that substantiation is always required of all advertisers*, but with the narrow—and by that point consistent—contention that it represented "a 'fencing in' provision justified by the petitioners' false representations that they had scientific evidence which formed a reasonable basis" for the claims it had previously made.[51] The Court affirmed the order, but expressly found that it "is ***as extreme a fencing in provision as we would sustain***," but one that was "justified in this case by the egregiousness of past misrepresentations and the propensity of the principal respondents to violate the FTC Act."[52] Yet this "extreme fencing in provision" is indistinguishable from what the Commission now purports to require of every advertiser—including Defendants—in every instance.

None of these decisions, or the Commission's position in these cases, make any sense if the Commission had believed, in any of these cases, that the FTC Act allowed it to impose substantiation requirements on all commercial speakers *before* they are adjudicated wrongdoers. This fundamental change in *policy* could not be justified by the language of the statute itself, because that language was static in the sixty years predating *Pfizer* and remained static in the years after *Pfizer* when the Commission continued to impose substantiation requirements only on adjudicated wrongdoers. Indeed, inasmuch as the Commission itself has previously argued that the substantiation requirement was lawful only because the defendant had already broken the law, the Commission tacitly acknowledged that no such requirement could be imposed on those who—like Xlear here—had never been found to have violated the FTC Act. At a minimum, it is

[50] *Id.* at 305.
[51] *Id.*
[52] *Id.* (emphasis added).

clear that the Commission did not believe, or at least argue, that the language of the FTC Act itself allowed it to impose substantiation requirements on parties who had not yet broken the law. Yet that is precisely what the Commission has done since and seeks to do in this case.

The only explanation for this change in posture is that the Commission's *interpretation* of the statute changed—not the language of the statute itself. The Commission's changing interpretations of the statute should not displace a plain reading of the statute itself.

III. THE FTC'S INTERPRETATION CONSTITUTES AN IMPERMISSABLE "MAJOR FEDERAL ACTION" LACKING EXPLICIT STATUTORY AUTHORIZATION

The FTC has imposed its substantiation fiat on a vast cross section of the American economy and American lives—encompassing everything from nasal sprays (this case); to dietary supplements; to home construction materials.[53] In 2023, as this case proceeded, the FTC issued similar substantiation violation warnings to over 670 companies, including Abbott Labs, Bayer Corp., Cargill, Inc., Costco, Goop, Pepsi Co., Zurvita, Inc.—literally an A to Z of the American economy.[54] By any measure—lives impacted, percent of the economy effected—the scope of the FTC's actions here is vastly larger than the regulations the Supreme Court overturned as unauthorized under the major Federal action doctrine in *West Virginia v. EPA*, 597 U.S. 697, 701 (2022).

In adopting its current position, the Commission has unilaterally discarded years of its own jurisprudence (requiring substantiation only of adjudicated wrongdoers), decades of administration of the FTC Act where no such requirement had even been discussed, let alone

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[53] *See* *Basic Research, LLC v. FTC*, 807 F. Supp. 2d 1078 (D. Utah 2011); *FTC v. Innovative Designs, Inc.*, No. 20-3379, 2021 WL 3086188 (3d Cir. July 22, 2021).

[54] FTC, List of April 2023 Recipients of the FTC's Notice of Penalty Offenses Concerning Substantiation Product Claims, updated May 11, 2023, available at https://www.ftc.gov/system/files/ftc_gov/pdf/Published-list-Recipients.pdf.

imposed, and centuries of caselaw placing the burden of proof squarely on the plaintiff—including the government—absent an express statutory direction to the contrary. Most importantly, the FTC has strayed far beyond what the FTC Act authorizes. "A decision of such magnitude and consequence rests with Congress itself, or an agency acting with clear delegation from that representative body."[55] The Supreme Court in *West Virginia* continued, "[a]gencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an open book to which the agency may add pages and change the plot line."[56]

The FTC Act provides no authorization for the FTC's action. The word substantiation appears nowhere in the entire FTC Act. Nor does the concept of substantiation. The Commission has not merely "add[ed] pages" but an entire chapter to the FTC Act, fundamentally remaking the law of deceptive advertising, and censoring legitimate speech and flipping the burden of proof while it's at it. The Commission has overreached. When the Commission purported to require substantiation in order for claims not to be deceptive, it was "asserting highly consequential power beyond what Congress could reasonably be understood to have granted."[57] The Commission's position should be rejected as a major Federal action lacking specific statutory authority.

IV. EVEN IF THE FTC ACT ALLOWS THE COMMISSION TO REQUIRE SOME SUBSTANTIATION, THE "RANDOMIZED CLINICAL TRIAL" STANDARD IS LEGALLY AND FACTUALLY BASELESS

Even were we to cast aside all of the above analysis and were to accept the manufacturing of a substantiation concept into the FTC Act, the Commission's claims still fail because there is no statutory basis whatsoever for the Commission's position, integral to its claims, that only

[55] *West Virginia*, 597 U.S. at 735.
[56] *Id.* at 722 (cleaned up).
[57] *Id.* at 701.

published, randomized clinical trials will suffice or supply a "reasonable basis" for the claim.

As a threshold matter, and beginning again with the plain language of the FTC Act, nothing in the statute itself remotely suggests that claims are deemed misleading if they are not supported by trials at all, let alone "randomized clinical trials." It is also clear that Congress could not possibly have intended to impose a standard of randomized clinical trials when the FTC Act was enacted because the concept of "randomized clinical trials" didn't even exist at that time.[58]

Moreover, the very notion that randomized clinical trials are the *only* means by which a party can substantiate a claim is both illogical and itself, ironically, scientifically baseless.[59] In fact, the Commission itself noted in *Pfizer* that something other than a randomized clinical trial could provide a "reasonable basis" for product claims. For example, the Commission opined that the existence of "a valid efficacy test for a competing product of similar composition which was known to and verified by respondent . . . might have provided a reasonable basis for similar efficacy claims for [the respondent's product]."[60] The Commission also acknowledged (1) "that medical literature might, in some instances, be sufficient basis for making affirmative product claims," and (2) "the general state of medical knowledge at the time the claims were made,

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[58] It is well documented that the first double blind controlled drug trial was conducted in 1943—*three decades after the FTC Act became law*, and five years after it was amended to include "unfair" as well as "deceptive acts or practices"—when the UK Medical Research Council conducted a trial of patulin for treatment of the common cold. *See* "Evolution of Clinical Research: A History Before and Beyond James Lind, Pespect Clin Res., 2010 Jan-Mar; 1(1): 6-10, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3149409/.

[59] *See, e.g.*, "Masks During Pandemics Caused by Respiratory Pathogens – Evidence and Implications for Action," JAMA Network Special Communication, published Oct. 31, 2013 (available here: https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2811136) ("Many effective public health policies have never been assessed in randomized clinical trials; such trials are not the gold standard for the efficacy of all interventions.").

[60] *Pfizer* at *33.

regardless of how that knowledge was ascertained" might also supply a "reasonable basis" for product claims.[61] Thus, while the Complaint's allegations rest on the position that only a randomized clinical trial can provide the "reasonable basis" for Defendants' product claims, that position is not grounded in the language or history of the FTC Act, and is wholly inconsistent with the Commission's own prior statements.

Moreover, the only Federal Circuit Court that has asked this very question—whether the plain language of the FTC Act allows the Government to punish claims if not supported by double blind, placebo-controlled studies—has definitively answered it in the negative. In *FTC v. QT, Inc.*, 512 F.3d 858 (7th Cir. 2007), the Seventh Circuit explained:

> Nothing in the Federal Trade Commission Act, the foundation of this litigation, requires placebo-controlled, double-blind studies. The Act forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. ***The burden is on the Commission to prove that the statements are false.***[62]

The court then provided an illustrative example:

> Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable *how much* the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. **Placebo-controlled, double-blind testing is not a legal requirement for consumer products.**[63]

It is also noteworthy that the FDA has made and is making claims about COVID-19 vaccines that are admittedly not based on randomized clinical trials. For example, last fall the FDA was promoting the use of updated COVID-19 vaccines and, in so doing, extolled the "[e]vidence [that] supports the benefits of this year's updated COVID-19 vaccines: [1] People

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[61] *Id.* at *33.
[62] *Id.* at 861 (emphasis added).
[63] *Id.* (bold added, italics in original).

vaccinated with Moderna's updated COVID-19 vaccine showed a strong immune response against common variants. [2] ***In laboratory studies, Novavax's and Pfizer's updated COVID-19 vaccine also produced strong immune responses, which brings better protection against severe illness, hospitalization, and death.***"[64] FDA admits there are no randomized clinical trials—only "laboratory studies"—proving that the updated Novavax and Pfizer vaccines "bring better protection against severe illness, hospitalization, and death." Yet it is still making claims to that effect based on other science, stressing the importance of "evaluat[ing] the totality of evidence." Because that is what good scientists do—they rely on a variety of different kinds of information and data to reach various conclusions.[65]

To suggest that the FDA's statements—and those of the companies promoting the FDA-approved vaccines—are not just "misleading", but in violation of the FTC Act, because they aren't backed by randomized clinical trials, is absurd. But that is precisely what the Commission would have to argue here in order to avoid judgment on the pleadings. Either that or the Commission has to admit that the law imposes far more onerous standards on citizens than it would impose on the government itself, and the pharmaceutical companies it favors.

Because there is no statutory basis for the Commission to demand that claims be

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[64] 5 Things You Should Know about COVID-19 Vaccines | NCIRD | CDC (last accessed Aug. 6. 2024) (emphasis added).

[65] It is important for the Court to note that this is not, even by the Commission's own admission, a case in which there is no support for the claims at issue. *See, e.g.,* Complaint ¶¶ 26-27 (discussing two of the many studies upon which Defendants relied in making product claims). Moreover, the body of science, and thus the "totality of evidence," supporting the claims at issue continues to grow, including through randomized, controlled, clinical trials of products similar (equivalent) to Xlear. *See, e.g.*, "Nasal sprays and behavioural interventions compared with usual care for respiratory illness in primary care: a randomised, controlled, open-label, parallel-group trial," The Lancet Online, Published July 11, 2024 (available here: https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(24)00140-1/fulltext) (finding use of nasal sprays significantly reduced "the number of days of illness" in persons with respiratory illnesses).

supported by randomized clinical trials, and where the absence of such trials is the only basis on which the Commission contends Defendants' claims violate the FTC Act, the Complaint fails on its face to state an actionable claim.[66] Judgment on the pleadings is warranted.

CONCLUSION

For the foregoing reasons, this Motion should be granted.

Respectfully Submitted this 30th day of September 2024.

PRICE PARKINSON & KERR, PLLC

/s/ Roanld F. Price
Attorneys for Defendants

[66] As Judge Waddoups of this Court has concluded, even in circumstances where the Commission has entered into a Consent Agreement which contains a fencing-in provision requiring that a seller have "competent and reliable scientific evidence" (as the Commission had defined that term for a number of years) in order to make advertising claims for dietary supplements, that standard did not require randomized, double-blind, placebo-controlled clinical trials. *See, e.g., Basic Research, LLC v. FTC*, Case No. 2:09-cv-0779- W, 21 (D. Utah Nov. 25, 2014). Fencing-in provisions are designed to hold wrongdoers to a ***higher*** standard than the law ordinarily requires, not a lower one. It would be nonsensical for the Basic Research Consent Agreement, and the many other similar consent agreements the FTC had previously entered into with numerous other parties, to contain a fencing-in provision that imposes a *lower* substantiation requirement than that which the Commission now claims is required under the FTC Act.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 30, 2024, the forgoing document was electronically filed using the Court's ECF system which will automatically serve electronic copies on all counsel of record.

/s/ Angela Johnson
Angela Johnson